K020714
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JUL 1 2002

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, NH 03452
Telephone Number (603) 532-7706
Fax Number (603) 532-8211
Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Urological Catheter & Accessories

Common Name: Urinary Catheter

Proprietary Name: Rüsch FloNeil (coated, with Water Pack) and Rüsch FloCath Introgel (uncoated, without Water Pack).

Classification: Class II medical device, 78 KOD, 21CFR 876.5130

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch FloNeil/Flocath IntroGel is substantially equivalent in materials, design and use to Rüsch MMG/O'Neil Catheter Set and the MMG O'Neil Urinary Catheter.

4. Description of the Device.

The Rüsch FloNeil (coated, with Water Pack) / Rüsch Flocath IntroGel (uncoated, without Water Pack) - consists of a tubular PVC catheter, a split introducer, a silicone introducer tip, introducer cap, lubrication jelly and a pack of 15ml saline (for FloNeil -coated product) inside a closed urine collection bag.

5. Intended Use of the Device.

Aseptic Intermittent Self-Catheterization.

6. Summary of Technological Characteristics.

The device is equivalent in design and intended use with Rüsch MMG/O'Neil Catheter Set and the MMG O'Neil Urinary Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Mr. Rick Lykins
Group RA Manager – US
Rüsch International
Tall Pines Park
JAFFREY NH 03452

Re: K020714
Trade/Device Name: Rüsch FloNeil; FloCath IntroGel
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 GBM
Dated: June 13, 2002
Received: June 14, 2002

Dear Mr. Lykins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020714

Device Name: Rüsch FloNeil/FloCath IntroGel

Indications for Use:

Aseptic Intermittent Self Catheterization.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use
(Per 21 CFR 801.109)

David A. Syrowski

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020714